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10/538,840	03/01/2006	Joachim Schmitt	SCHM3001/REF	8834

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,840	Applicant(s) SCHMITT ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 18, 23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17, 18, 23, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 2, 4, 5, 7-9, 17 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Non-compliant Amendment, received 10 May 2007, is acknowledged. Claims 3, 4, 6, 10, 11, 12, 13, 17, 23 have been amended. Claims 16, 19-22, and 24 have been canceled.
2. Claims 1-15, 17, 18, 23, 25, and 26 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Pages 1-3, 14-16, 33, and 34 contain reference citations which are incomplete, i.e., they only list author and year.

Page 3, line 9, "myelinisation" should be "myelinization"; line 19 "*helicobacter pylori*" should be "*Helicobacter pylori*".

Page 5, lines 6 and 8, "hybridise" should be "hybridize"; line 19, "characterised" should be "characterized".

Page 6, line 4, "characterised" should be "characterized".

Page 7, lines 6 and 9, "characterised" should be "characterized".

Page 9, last line, "eucaryontic" should be "eucaryotic".

Page 10, line 1, "procaryontic" should be "procaryotic"; line 9, "characterised" should be "characterized".

Page 13, line 18, what is "de-" to mean?

Page 15, line 15, "dehydrolyse" should be "dehydrolyze"; line 19, "fig." should be "Fig."; line 26, "utilisation" should be "utilization".

Page 16, line 12, "characterised" should be "characterized".

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Page 20, lines 13, 24, and 25, "hybridisation" should be "hybridization"; line 20, "synthesised" should be "synthesized".

Page 21, line 5, "characterised" should be "characterized"; line 6, "also by produced" should be "also be produced"; line 13, "hybridises" should be "hybridizes".

Page 22, lines 6 and 14, "hybridise" should be "hybridize"; line 13, "synthesised" should be "synthesized"; line 21, "to be understand as" should be "to be understood as"; lines 22 and 25, "hybridised" should be "hybridized"; line 25, "hybridisation" should be "hybridization".

Page 23, line 15, "synthesised" should be "synthesized"; line 23, "hybridise" should be "hybridize"; line 24, "inhibitied" should be "inhibited".

Page 27, line 20, "procaryontic" should be "procaryotic".

Page 28, line 22, "homolous" should be "homologous"; line 27, "Escherichia" should be in italics.

Page 29, lines 1 and 2, the bacterial names should be in italics.

Page 31, line 8, "lysated" should be "lysed".

Page 32, line 2, "summarised" should be "summarized".

Page 33, line 17, "neutralised" should be "neutralized".

Appropriate correction is required.

Drawings

4. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."

Figures 1 and 3 do not contain the required sequence identifiers. Appropriate correction is required.

5. Figure 1 is objected to because the figure is labeled "Bild" 1.

Figure 3 is objected to because the figure is labeled "Bild" 3.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claim 2 is objected to because of the following informalities: line 2, "catalyses" should be "catalyzes". Appropriate correction is required.

7. Claim 4 is objected to because of the following informalities: line 1, "hybridises" should be "hybridizes". Appropriate correction is required.

8. Claim 5 is objected to because of the following informalities: line 1, "hybridises" should be "hybridizes"; line 3, "micoorganisms" should be "microorganisms"; line 3, "Trypanosoma" should be in italics. Appropriate correction is required.

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9. Claim 7 is objected to because of the following informalities: line 2, "characterised" should be "characterized". Appropriate correction is required.
10. Claim 8 is objected to because of the following informalities: line 1, "characterised" should be "characterized". Appropriate correction is required.
11. Claim 9 is objected to because of the following informalities: line 1, "characterised" should be "characterized". Appropriate correction is required.
12. Claim 17 is objected to because of the following informalities: line 2, "characterised" should be "characterized". Appropriate correction is required.
13. Claim 18 is objected to because of the following informalities: line 1, "characterised" should be "characterized". Appropriate correction is required.

Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims read on products of nature, i.e., nonisolated polynucleotides which read on whole bacterial polynucleotides within live bacteria.

16. Claims 6-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims read on products of nature, i.e., nonisolated polypeptides which read on whole bacterial polypeptides within live bacteria.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 3, 6, 7, 10-15, 17, 18, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is uncertain what the metes and bounds are for a sequence being "in accordance with" another sequence.

19. Claims 3 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to sequences which are "derived" from other polynucleotides. It is unclear what the metes and bounds of this term encompasses.

20. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a polypeptide encoded by a polynucleotide which "comprises" a nucleic acid sequence in accordance with the polynucleotide of claim 1. Because of the open language of the claim, i.e., "comprises", the encoding nucleic acid sequence may contain

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unknown regions on either end of the polynucleotide of claim 1. Thus, the claim polypeptide may come from these unknown regions and therefore be unknown in sequence or function.

21. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim is drawn to a "pharmaceutical" composition.

M.P.E.P. §2164.01(c), paragraph 3, recites:

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *in re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Steadman's Medical Dictionary (26th Edition, 1995) defines "pharmaceutical" as "relating to pharmacy or to pharmaceuticals"; "pharmacy" as "the practice of preparing and dispensing drugs", and "drug" as "Therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease"

While the definition of "pharmaceutical" is broad, it is not so broad to cover any use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered.

In the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered.

22. Claims 6, 7, 12, 17, 18, 23, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 7, 12 recite the phrase "functional equivalents".

The specification, page 17, lines 1-6, defines "functional equivalents" as polypeptides different to these which, moreover, have the desired biological activity in accordance with the above definition, and that "functional equivalents" should be understood as being mutants which in at least one of the sequence positions specified above have an amino acid other than that precisely specified but which despite this have one of the biological activities specified here. Thus, the definition is unclear because: 1) it designates the term as a polypeptide which is merely "different to" the listed polypeptides, and 2) it designates the term as mutants which have any/all amino sequence changes but which have one of the biological activities specified "here" but which is not actually designated as required biological activities.

Claims 17, 18, 23, and 26 depend from the claims, but do not clarify the issue.

23. Claim 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear specifically to what the claims are referring by utilizing the term "Material" or "Materials".

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no period at the end of the claim, and therefore the unfinished claim is indefinite. The period was deleted by the Preliminary Amendment.

24. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phraseology of the claim renders it unclear when the claim recites "if required". It is not clear what is or is not required for the isolation of said enzyme.

Conclusion


25. No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

June 18, 2007